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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/577,264	05/22/2000	John S. Patton	0002..12	4287

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NEKTAR THERAPEUTICS
150 INDUSTRIAL ROAD
SAN CARLOS, CA 94070

EXAMINER

LUKTON, DAVID

ART UNIT	PAPER NUMBER
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1654

MAIL DATE	DELIVERY MODE
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08/29/2007

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Continuation of Disposition of Claims:

Claims withdrawn from consideration are 20,21,24,26,28-34,36,38,39,41,46-55,58,59,61,62 and 68.

Office Action Summary

Application No.

09/577,264

Applicant(s)

PATTON, JOHN S.

Examiner

David Lukton

Art Unit

1654

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 01 August 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 20,21,24,26,28-34,36,38,39,41 and 46-68 is/are pending in the application.
- 4a) Of the above claim(s) See Continuation Sheet is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 56,57,60 and 63-67 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- ☐ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☒ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date 8/1/06
- ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- ☐ Notice of Informal Patent Application
- ☐ Other: _____

Pursuant to the directives of the response filed 8/1/06, claims 56 and 66 have been amended. Claims 20, 21, 24, 26, 28-34, 36, 38, 39, 41, 46-68 are now pending.

Claims 20, 21, 24, 26, 28-34, 36, 38, 39, 41, 46-55, 58, 59, 61, 62, 68 remain withdrawn pursuant to the restriction or species election.

Applicants have implied that the examiner should state that he would incur a "serious burden" if he were required to examine all of the claims pending in the application. In response, the examiner now states that he would indeed incur such a burden

Applicants' arguments filed 8/1/06 have been considered and found not persuasive.

Claims 56, 57, 60, 63-67 are examined in this Office action.



The following is a quotation of the first paragraph of 35 U.S.C. §112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it in such full, clear, concise and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 56, 57, 60, 63-67 are rejected under 35 U.S.C. §112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

The claims encompass "treating" a subject who is healthy, as well as treating a subject who has a disease of some kind. As such, any disease would be included.

Several diseases come to mind such as cancer, AIDS and Alzheimer's disease. How do applicants propose to treat such diseases?

Then there is the matter of patients suffering from hyperparathyroidism. Clearly, attempting to treat a subject suffering from this disorder is only going to exacerbate his condition. At the very least, "unpredictable" results will be obtained.

As stated in *Ex parte Forman* (230 USPQ 546, 1986) and *In re Wands* (8 USPQ2d 1400, Fed. Cir., 1988) the factors to consider in evaluating the need (or absence of need) for "undue experimentation" are the following: quantity of experimentation necessary, amount of direction or guidance presented, presence or absence of working examples, nature of the invention, state of the prior art, relative skill of those in that art, predictability or unpredictability of the art, and breadth of the claims.

Accordingly, "undue experimentation" would be required for treatment of most diseases, but particularly hyperparathyroidism.



Claims 56, 57, 60, 63-67 are rejected under 35 U.S.C. §112 second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 56 and 66 are indefinite as to the objective of the “treating” and to the outcome of a successful treatment. If the composition is administered to a healthy person, and no discernable change in his health condition occurs as a result, are the requirements of the claims met?

Claim 65 recites that the composition in question “comprises” a powder. At the same time, claim 56, upon which claim 65 depends, recites that the composition in question “consists essentially of” the indicated ingredients. Thus, the propriety of the claim dependence is called into question. Consider the following claim:

*100. The method of claim 56, wherein the composition that is administered does not merely consist essentially of the PTH fragment, the bulking agent and the propellant, but rather, comprises those three components, and therefore any other compound can be present, and steroids are not excluded,
subject only to the proviso that the composition must be in powder form.*

Claim 100 is intended as an exaggerated version of claim 65. Claim 100 is provided in an effort to show how one could reasonably interpret claim 65. The point is that claim 65 does indeed permit other components to be present (in addition to the PTH fragment, the bulking agent and the propellant).



Claim 65 is rejected under 35 U.S.C. 112, fourth paragraph, as being of improper dependent form for failing to further limit the subject matter of a previous claim.

Claim 65 recites that the composition in question can comprise a PTH fragment, a bulking agent and the propellant, as long as that composition is in powder form. By contrast, claim 56, upon which claim 65 depends, recites that the composition in question must “consist essentially of” the PTH fragment, a bulking agent and the propellant. [*Pfizer Inc v. Ranbaxy Labs*, 79 USPQ2d 1583(Fed. Cir. 2006)].



The following is a quotation of 35 USC §103 which forms the basis for all obviousness rejections set forth in the Office action:

A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Subject matter developed by another person, which qualifies as prior art only under subsection (f) and (g) of section 102 of this title, shall not preclude patentability under this section where the subject matter and the claimed invention were, at the time the invention was made, owned by the same person or subject to an obligation of assignment to the same person.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103, the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made, absent any evidence to the contrary. Applicant is advised of the obligation under 37 C.F.R. 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of potential 35 U.S.C. 102(f) or (g) prior art under 35 U.S.C. 103.

Claims 56, 57, 60, 63, 64, 65, 67 are rejected under 35 U.S.C. §103 as being unpatentable over Wang (USP 5,011,678) in view of Neer (USP 4,698,328).

As indicated previously, Wang discloses (col 7, line 17) that PTH can be administered in aerosol form. There are also several references to fluorocarbon, chlorofluorocarbon and hydrocarbon propellants. Wang does not disclose fragments of PTH. Neer discloses (col 4, line 50+) the use of PTH(1-34) and advantages associated therewith. Thus, it would have been obvious to treat osteoporosis by inhaling PTH(1-34).

In response to the foregoing, applicants have argued that the term "consisting essentially of" is effective to exclude all compounds other than the PTH peptide, the bulking agent and the propellant. However, applicants are not correct. As it

happens, the steroids mentioned in Wang are not "essential" to the composition. Applicants have also argued that if Neer discloses that if hydroxylated vitamin D is omitted from the composition, the composition then becomes impossible to administer by inhalation. However, this is not actually disclosed by Neer.

Further, even if claim 56 were amended to recite the term "consisting of", rather than "consisting essentially of", the rejection would still be valid against claim 65, which is drawn to a method of using a composition that "comprises" the indicated ingredients.

The rejection is maintained.



Claims 56, 57, 60, 63, 64, 65, 67 are rejected under 35 U.S.C. §103 as being unpatentable over Wang (USP 5,011,678) in view of Morita (USP 4,656,250).

As indicated previously, Morita discloses that the peptide [Nle⁸, Nle¹⁸, Tyr³⁴] PTH(1-34) has advantages over PTH(1-34). Morita does not disclose administration by inhalation; however, this is disclosed in Wang. Thus, it would have been obvious to treat osteoporosis by inhaling the PTH(1-34) analog that is disclosed in Morita.

In response to the foregoing, applicants have argued that the term "consisting essentially of" is effective to exclude all compounds other than the PTH peptide, the bulking agent and the propellant. However, applicants are not correct.

As it happens, the steroids mentioned in Wang are not "essential" to the composition. Applicants have also implied that in considering the teachings of a patent document, one

should consider only the examples, and disregard all other teachings. However, applicants are not correct about this proposition.

The rejection is maintained.

✦

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to David Lukton whose telephone number is 571-272-0952. The examiner can normally be reached Monday-Friday from 9:30 to 6:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Cecilia Tsang, can be reached at (571)272-0562. The fax number for the organization where this application or proceeding is assigned is 571-273-8300.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 571-272-1600.



DAVID LUKTON, PH.D.
PRIMARY EXAMINER